

Patent

Docket No. 9222.16632CIP

SYSTEMS AND METHODS  
FOR MONITORING AND CONTROLLING  
USE OF MEDICAL DEVICES

RELATED APPLICATION

5 This application is a continuation-in-part  
of co-pending United States Patent Application  
Serial Number 09/026,296, filed February 19, 1998,  
and entitled "Method for Treating Sphincter." This  
application is also a continuation-in-part of co-  
10 pending provisional United States Patent Application  
Serial Number 60/152,749, filed September 8, 1999  
and entitled "Systems and Methods for Monitoring and  
Controlling Use of Medical Devices."

FIELD OF THE INVENTION

15 The invention is directed to systems and  
methods for monitoring and controlling use of  
medical devices.

BACKGROUND OF THE INVENTION

20 Use of medical devices intended to treat or  
diagnose conditions of the body can sometimes  
generate stress on the material or materials from  
which the devices are made. The material stress can  
alter the physical characteristics of the devices,  
making future performance of the devices  
25 unpredictable.

In addition, exposure to blood and tissue  
during use can entrap biological components on or

within many medical devices. Despite cleaning and subsequent sterilization, the presence of entrapped biological components can lead to unacceptable pyrogenic reactions.

5           The effects of material stress and damage caused during a single use of a medical device, coupled with the possibility of pyrogen reactions even after resterilization, reasonably justify imposing a single use restriction upon many medical  
10        devices.

SUMMARY OF THE INVENTION

          The invention provides systems and methods for monitoring and controlling use of medical devices.

15           One aspect of the invention provides a kit containing a device for treating a tissue region. The kit also includes, packaged with the device, a usage key card. The usage key card comprises a storage medium, which is formatted to contain an  
20        identification code unique to the usage key card. The usage key card is adapted to be read by a remote reader, to download the identification code for processing by a controller for the device. Preestablished prior use criteria govern the  
25        processing of the identification code by the controller. Meeting the criteria permits operation of the device. Conversely, not meeting the criteria disables use of the device.

          In one embodiment, the storage medium is  
30        also formatted to retain data generated by the controller during permitted operation of the device. The data, e.g., pertains to operating conditions of

the device, creating a procedure log. In this arrangement, the usage key card is adapted to be read by a reader, to download the procedure log for further processing by a separate data processing device.

Another aspect of the invention provides systems and methods for processing the identification code by the controller. The systems and methods cause the controller to create a table in memory in which unlike identification codes are registered as they are downloaded by the reader. The systems and methods enable operation of the device when a new identification code is registered in the table.

According to this aspect of the invention, the systems and methods cause the controller to compare a given identification code downloaded by the reader to all identification codes registered in the table. The systems and methods cause the controller to register the given identification code in the table when the given identification code does not match any identification code in the table. In this instance, operation of the device is permitted. Conversely, the systems and methods cause the controller not to register the given identification code when the given identification code matches an identification code already in the table. In this instance, operation of the device is not permitted.

In an embodiment that pertains to both aspects of the invention, the device operates to apply radio frequency energy to the tissue region.

Features and advantages of the inventions